Arch Chemicals, Inc.
501 Merritt 7, P.O. Box 5204
Norwalk, CT 06856-5204
Tel: 203.229.2693
Fax: 203.229.3543
Internet: sjbarbee@archchemicals.com

Steven J. Barbee, Ph.D.
Director, Environmental Hygiene and Toxicology

201-14950

ARCH

Michael Leavitt
Administrator, US EPA
PO Box 1473
Merrifield, VA 22116

December 17, 2003

Re: Chemical Right-to-Know HPV Chemical Challenge Program

Dear Administrator Leavitt:

On behalf of Arch Chemicals, Inc. (Arch), I am pleased to submit the test plan and robust summaries for polyphosphoric acid esters of triethanolamine, sodium salts (CAS No. – 68131-72-6).

Enclosed with this letter are two copies of the test plan and robust summaries – one in hard copy and one on computer diskette in Microsoft Word format. The HPV registration number for Arch is

Arch understands that this information will be posted on the Internet for comments for a period of 120 days. Please forward comments to me at the above address.

Sincerely yours,

Steven J. Barbee, Ph.D., DABT, CIH

201-14950

HIGH PRODUCTION VOLUME (HPV) CHALLENGE PROGRAM

TEST PLAN

AND ROBUST SUMMARIES

FOR

POLYPHOSPHORIC ACID ESTERS OF TRIETHANOLAMINE, SODIUM SALTS

CAS NO. – 68131-72-6

PREPARED BY:

ARCH CHEMICALS, INC.

December 17, 2003

TABLE OF CONTENTS

OVERVIEW

Arch Chemicals, Inc. (Arch) hereby submits the test plan and robust summaries for polyphosphoric acid esters of triethanolamine, sodium salts (CASRN – 68131-72-6) under the Environmental Protection Agency's High Production Volume Chemical Challenge Program. It is the intent of Arch to use existing data for triethanolamine (CASRN – 102-71-6) to adequately fulfill the Screening Information Data Set (SIDS) for the physical/chemical endpoints, environmental fate, ecotoxicity and human health-related toxicology.

Polyphosphoric acid esters with triethanolamine is an amber liquid having a very mild ammonia odor. This chemical is an aqueous surfactant solution containing a partially neutralized mixture of triethanolamine polyphosphoric acid esters used to impart corrosion and scale inhibition properties to water recirculating systems such as air conditioning cooling tower, secondary oil recovery operations, boiler equipment, and other water treatment applications where scale build-up can be a problem.
The pH of a 5 % solution in neutral distilled water is in the range of 4-6.

The average composition of the final product can be calculated from the result of (a) direct analysis of the product for orthophosphate, which is a direct measure of the amount of sodium dihydrogen phosphate byproduct formed by competitive reactions, (b) direct analysis of the product for total solids and (c) a knowledge of the amounts of raw materials charged at the beginning of the reaction. Specifications for this chemical are 70% minimum total solids and 20% maximum orthophosphate. At these limits, the average product composition calculates to be a mixture of diester and monoester in a mole ratio of about 3:2. As orthophosphate goes down (but total solids stay the same) this ratio gets larger, i.e. there is more diester and less monoester, until at an orthophosphate level of 12.2%, the product is all diester. Typical total solids are 70-72% and the typical orthophosphate level is 14-18%. The actual product composition, due to the statistical randomness of the competitive hydrolysis reactions, will vary somewhat from this theoretical average and will probably include small amounts of both triester and free triethanolamine.

JUSTIFICATION FOR USE OF TRIETHANOLAMINE AS A SURROGATE FOR POLYPHOSPHORIC ACID ESTERS OF TRIETHANOLAMINE

Polyphosphoric acid esters with triethanolamine, sodium salts is manufactured as an aqueous solution from polyphosphoric acid, triethanolamine and sodium hydroxide. This material is a mixture of tri-, di-, and monophosphate esters of triethanolamine and consequently is classified with a range of molecular weight. Thus, the molecular weight ranges from 251 for the sodium salt of the monophosphate ester to 455 for the sodium salt of the triphosphate ester. The molecular weight for triethanolamine is 149. The difference in molecular weight is due to the varying amount sodium and phosphate groups. Triethanolamine is a pale yellow hygroscopic viscous liquid with a melting point of 21^{o}C. It has a vapor pressure of <0.01 mm Hg at 20^{o}C (Howard, 1990). Both triethanolamine (Howard, 1990) and polyphosphoric acid esters with triethanolamine, sodium salts are miscible with water. The molecular structure of the two chemicals is similar. In the synthesis of polyphosphoric acid esters with triethanolamine, sodium salts the structure of triethanolamine is modified only by the presence of a phosphate group with sodium at the end of one or more of the ethanol groups.

The presence of phosphate groups esterified with triethanolamine would probably facilitate the excretion of this material from the body. The phosphate groups would not increase the toxicity of triethanolamine and, in all likelihood, would decrease it to both mammals and aquatic organisms. Metabolically, polyphosphoric acid esters with triethanolamine, sodium salts could undergo hydrolysis resulting in removal of one or more phosphate groups from triethanolamine. The phosphate groups would then be available to enter the general phosphate pool of the body. The toxicity of phosphate is low and in fact, phosphate is critical to normal physiological function of the body. Removal of all the phosphate groups results in triethanolamine, the chemical that will serve as the surrogate to define the physical/chemical properties, environmental fate, aquatic toxicity and mammalian toxicity of polyphosphoric acid esters with triethanolamine, sodium salts.

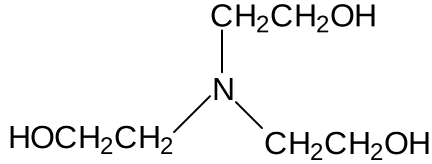
Comparison of the chemical structure between polyphosphoric acid esters with triethanolamine, sodium salts and triethanolamine

- **Polyphosphoric acid esters with triethanolamine, sodium salts**

$$_{x}(HOCH_2CH_2){-}N{-}(CH_2CH_2OPO_3HNa)_{y}$$

Where
$x = 1 - 2$
$y = 1 - 2$

- **Triethanolamine**



TEST PLAN SUMMARY

Polyphosphoric acid esters with triethanolamine, sodium salts CAS # 68131-72-6	Information	OECD Study	Other	Estimation	GLP	Acceptable	New Testing Required
STUDY	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N	Y/N
PHYSICAL-CHEMICAL DATA							
Melting Point	Y	N	Y	N	N	Y	N
Boiling Point	Y	N	Y	N	N	Y	N
Vapor Pressure	Y	N	Y	N	N	Y	N
Partition Coefficient	Y	N	Y	N	N	Y	N
Water Solubility	Y	N	Y	N	N	Y	N
ENVIRONMENTAL FATE DATA							
Photodegradation	Y	N	Y	N	N	Y	N
Stability in Water	N	N	Y	Y	N	Y	N
Biodegradation	Y	N	Y	N	N	Y	N
Transport between Environmental Compartments (Fugacity)	Y	N	Y	Y	N	Y	N
ECOTOXICOLOGICAL DATA							
Acute Toxicity to Fish	Y	N	Y	N	N	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	N	Y	N	N	Y	N
Toxicity to Aquatic Plants	Y	N	Y	N	N	Y	N
MAMMALIAN TOXICOLOGICAL DATA							
Acute Toxicity	Y	N	Y	N	N	Y	N
Repeated Dose Toxicity	Y	N	Y	N	N	Y	N
Genetic Toxicity							
Mutation	Y	N	Y	N	N	Y	N
Chromosomal Aberration	Y	N	Y	N	N	Y	N
Developmental Toxicity	Y	N	Y	N	N	Y	N
Toxicity to Reproduction	N	N	Y	Y	N	Y	N

TEST PLAN DESCRIPTION FOR EACH SIDS ENDPOINT

A. Physical/Chemical Endpoints for Triethanolamine

Melting Point – A value for this endpoint was obtained from a standard reference text (Howard, 1990).

Boiling Point – A value for this endpoint was obtained from a standard reference text (Howard, 1990).

Vapor Pressure – A value for this endpoint was obtained from a standard reference text (Howard, 1990).

Partition Coefficient – Values for this endpoint were obtained from company data (BASF, 1989 and 1991) and a standard reference text (Howard, 1990).

Water Solubility – A value for this endpoint was obtained from a standard reference text (Howard, 1990).

Conclusion – All endpoints have been satisfied by the utilization of data obtained from a reliable reference text or company data. Thus, no new testing is needed in the area of physical/chemical properties.

B. Environmental Fate Endpoints for Triethanolamine

Photodegradation – A value for this endpoint was obtained from a standard reference text (Howard, 1990) and from a computer estimation model (AopWin v.1.90, 2000).

Stability in Water – If released to water, triethanolamine should biodegrade. The half-life of this compound is expected to range from a few days to a few weeks depending on the degree of acclimation of the system. Bioconcentration in aquatic organisms, adsorption to suspended solids and sediments, and volatilization are not expected to be important fate processes in water. Triethanolamine does not decompose or hydrolyze in contact with water and there is no abiotic degradation (Howard, 1990).

Biodegradation – This endpoint was satisfied using data from studies published in the open literature (Gerike and Fischer, 1979; Zahn and Wellens, 1980). The data indicate that triethanolamine is inherently biodegradable. In the ready biodegradation tests, triethanolamine was readily biodegradable in the AFNOR (97% degradation based on DOC removal), STURM (91% degradation based on CO_2 evolution) and OECD Screening test (96% degradation based on DOC removal, but little degradation was observed in the MITI (14 day test; 2% removal based on BOD and Closed Bottle (0-9% removal based on BOD) (SIDS Initial Assessment Report). The SIDS Initial Assessment Report concluded that triethanolamine is readily biodegradable, possibly after a short acclimation period and that extensive removal due to biodegradation is to be expected in sewage treatment plants.

Fugacity – This endpoint was satisfied using data from intracompany correspondence (Comber, 1993. ICI Chemicals). Due to the high water solubility and low vapor pressure of triethanolamine, it is likely to partition preferentially into the water phase from which volatilization to the atmosphere is likely to be only a minor removal process. The low log Kow value indicates that bioaccumulation and adsorption onto soils/sediments is unlikely to occur.

Conclusion – All endpoints have been satisfied using actual data, through the use of EPA-acceptable estimation models, a standard reference text, or, in the case of stability in water, scientific judgment to support the position for testing requirements. No additional testing is needed in the area of environmental fate.

C. Ecotoxicity Endpoints for Triethanolamine

Acute Toxicity to Fish – This endpoint was satisfied using data from aquatic toxicity studies published in the open literature (Birdie et al., 1979; Geiger et al., 1987). Two freshwater species were used – *Carassius auratus and Pimelphales promelas*. The LC_{50} (24 to 48-hour exposure) was greater than 1000 mg/l to both species.

Acute Toxicity to Aquatic Invertebrates – This endpoint was satisfied using data from aquatic toxicity studies published in the open literature (Bringman and Kuhn, 1982; Bringman and Kuhn, 1987). The test species was *Daphnia magna*. The EC_{50} (24-hour exposure) was greater than 1000 mg/l.

Toxicity to Aquatic Plants – This endpoint was satisfied using data from aquatic toxicity studies published in the open literature (Amann and Stainhauser, 1986; Kuhn and Pattard, 1990). The test species was *Scenedesmus subspicatus*. The EC_{50} (72 to 96-hour exposure) ranged from 169 to 910 mg/l. The difference was dependent upon the pH with the non-neutralized triethanolamine exerting the greater toxicity.

Conclusion – All endpoints have been satisfied using actual data from literature sources. No additional testing is needed in the area of environmental fate.

D. Mammalian Toxicological Endpoints for Triethanolamine

Acute Toxicity – The studies that satisfy this endpoint were conducted prior to introduction of GLP. However, all studies (Oral LD_{50}, dermal LD_{50} and inhalation LC_{50}) to define the acute toxicological profile were conducted in accordance with currently accepted scientific principles and are considered reliable. The data indicate that triethanolamine is of low toxicity by the oral, dermal and inhalation routes of exposure. Oral LD_{50} values have been shown to range from approximately 5-10 g/kg (Smyth et al., 1951; Kindsvatter, 1940; Cosmetic Ingredient Review, 1983). The dermal LD_{50} is greater than 2 g/kg (Cosmetic Ingredient Review, 1983). The inhalation LC_{50} is greater than a saturated atmosphere (BASF AG, 1966)

Repeat Dose Toxicity – The studies to determine toxicity of triethanolamine from repeated exposure were conducted for a duration of 91 days (CTFA, 1976) or 2 years (Maekawa et al., 1986). In both studies the NOAEL was at least 1000 mg/kg. There was no evidence of gross or histopathological change that could be attributed to treatment. Also, triethanolamine was shown to be non-carcinogenic.

Genetic Toxicity

Mutation (bacterial) – This endpoint has been satisfied by two studies (Inoue et al., 1982; Mortelmans et al., 1986) using 4 strains (TA 98, TA 100, TA 1535 and TA 1537) of *Salmonella typhimurium*. Triethanolamine was not mutagenic in any of the tester strains.

Chromosomal aberration (mammalian, *in vitro*) – This endpoint was satisfied by a cytogenetic assay using Chinese hamster lung cells (Inoue et al., 1982). Triethanolamine did not induce chromosome aberrations in this test system.

Reproductive Toxicity – No studies have been conducted to specifically evaluate the effect of triethanolamine on reproductive performance. However, based on consideration of the repeat dose toxicity studies of at least 90 days duration, there were no abnormalities noted in the histopathological examination of reproductive organs. This fact, and the lack of effects on fetal development, allow the conclusion that triethanolamine would not be expected to produce adverse effects to reproductive performance and fertility.

Developmental Toxicity – This endpoint was satisfied using a developmental toxicity screening study according to the Chernoff-Kavlock method (Pereira et al., 1987). Based on the results from this test, triethanolamine does not impair development of the fetus.

Conclusion – The endpoints for acute toxicity and genetic toxicity have been satisfied with data from studies that were conducted utilizing methods that are similar to established guidelines and are scientifically appropriate. The endpoints of repeat dose toxicity, reproductive toxicity and developmental toxicity have not been satisfied. Studies will be conducted to supply data for these endpoints and they will be conducted according to OECD guidelines and GLP assurances.

SIDS DATA SUMMARY

Triethanolamine is a high boiling liquid that is miscible with water. It has a low vapor pressure and a low log K_{ow}. Due to the high water solubility and low vapor pressure, triethanolamine is likely to partition preferentially into the water phase from which volatilization to the atmosphere is likely to be only a minor removal process. The low log K_{ow} indicates that bioaccumulation and adsorption onto soils/sediment is unlikely to occur. Triethanolamine is readily biodegradable.

The ecotoxicity of triethanolamine is low regardless of the test organism. Fish exhibit the least sensitivity to this chemical with 96-hour LC_{50} values in the range of 5,000-10,000 mg/l. The toxicity to the water flea is also low with the 24-hour EC_{50} greater than 1,000 mg/l. Algae show the greatest sensitivity, but even so the 96-hour EC_{50} is almost 1,000 mg/l for neutralized triethanolamine.

Triethanolamine is of low toxicity following single exposures. It is not genotoxic or carcinogenic. It does not impair development of the fetus and does not produce toxicity to the reproductive system. Also, it is judged not to impair reproductive performance or fertility based on its lack of developmental toxicity and histopathological change to the reproductive organs.

The physical/chemical properties, environmental fate and aquatic and mammalian toxicological data for triethanolamine have been reviewed by the OECD High Production Volume Chemicals Program through a SIDS Initial Assessment Report (SIAR). Based on the evaluation of all the data presented in the SIAR, triethanolamine is presently considered of low priority for further work and moreover, no further toxicity testing is required.

The presence of esterified phosphate groups on triethanolamine is judged not to significantly alter the above characteristics of physical/chemical properties, environmental fate and aquatic and mammalian toxicity. Thus, it is the judgment of Arch Chemicals, Inc. that triethanolamine is an appropriate analog for use to predict the chemical/physical properties, environmental fate and aquatic and mammalian toxicity of polyphosphoric acid esters of triethanolamine, sodium salts (CASRN 68131-72-6).

The SIDS Initial Assessment Report concluded that triethanolamine is presently of low priority for further work and that no further toxicity testing is required.

EVALUATION OF DATA FOR QUALITY AND ACCEPTABILITY

The collected data were reviewed for quality and acceptability following the systematic approach described by Klimisch et al. (1997). The codification described by Klimisch specifies four categories of reliability for describing data adequacy. They are:

1. Reliable without restriction: Includes studies or data complying with Good Laboratory Practices (GLP) procedures, or with valid and/or internationally accepted testing guidelines, or in which the test parameters are documented and comparable to these guidelines.

2. Reliable with restrictions: Includes studies or data in which test parameters are documented but vary slightly from testing guidelines.

3. Not reliable: Includes studies or data in which there are interferences, or that use non-relevant organisms or exposure routes, or which were carried out using unacceptable methods, or where documentation is insufficient.

4. Not assignable: Includes studies or data in which insufficient detail is reported to assign a rating, e.g., listed in abstracts or secondary literature.

REFERENCES

1. AopWin v.1.90. (EPI Suite™ v.3.10). Downloadable at http://www.epa.gov/oppt/exposure/docs/episuitedl.htm. ©2000 U. S. Environmental Protection Agency.

2. Amann, W. and A. Stainhauser. 1986. Umweltforschungsplan des BMI, UFOPLAN Nr. 102 05 308. im Auftrag des Umweltbundesamtes.

3. BASF AG. Abteilung Toxikologie. Unpublished report. ZST-Nr. SV/307. 1966.

4. BASF AG. Labor fuer Umweltanalytik; unveroeffentlichte Untersuchung. 1989.

5. BASF AG. Analytisches Labor; unveroeffentlichte Untersuchung (J. Nr. 90P03095.03 vom 05.04.1991).

6. Birdie, A. L., C. J. M. Wolff and M. Winter. 1979. The Acute Toxicity of Some Petrochemicals to Goldfish. Water Res. 13: 623-626.

7. Bringman, G. and R. Kuhn. 1982. Z. Wasser Abwasser Forsch. 15: 6-11.

8. Bringman, G. and R. Kuhn. 1987. Results of the damaging effect of water pollutants on *Daphnia magna*. Z. Wasser Abwasser Forsch. 20: 161-166.

9. Comber, M. I. H. Zeneca Brixham Environmental Laboratory. Letter to M. G. Penman. ICI Chemicals & Polymers Limited. 1993.

10. Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine, Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235.

11. CTFA. 1976. Submission of data by CTFA (2-5-55). 91-Day subchronic oral toxicity using triethanolamine. Cited in CIR. 1983.

12. Geiger, D. L., L. T. Brooks and D. J. Call. Acute Toxicities for Organic Chemicals to Fathead Minnows (*Pimephales promelas)*. Volume V. Center for Lake Superior Environmental Studies, University of Wisconsin – Superior. 1984-1988.

13. Gerike, P. and Fischer, W. K. 1979. A Correlation Study of Biodegradability Determinations with Various Chemicals in Various Tests. ECETOX. Environ. Safety. 3: 159-173.

14. Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

15. Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. Mut. Res. 101: 305-313.

16. Kindsvatter, V. H. 1940. Acute and chronic toxicity of triethanolamine. J. Indus. Hyg. Toxicol. 22 (6): 206-212.

17. Klimisch, H.-J., Andreae, M. and Tillman, U. 1997. A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data. Regul. Toxicol. Pharmacol. 25, 1-5.

18. Kuhn, R. and M. Pattard. 1990. Results of the Harmful Effects of Water Pollutants to Green Algae (*Scenedusmus subspicatus)* in the Cell Multiplication Inhibition Test. Water Res. 24: 31-38.

19. Maekawa, A., H. Onodera, H. Tanigawa, K. Furuta, J. Kanno, C. Matsuoka, T. Ogiu and Y. Hayashi. 1986. Lack of Carcinogenicity of Triethanolamine in F344 Rats. J. Toxicol. Environ. Health. 19: 345-357.

20. Mortelmans, K., S. Haworth, T. Lawlor, W. Speck, B. Tainer and E. Zeiger. 1986. *Salmonella* Mutagenicity Tests: II. Results from the Testing of 270 Chemicals. Environ. Mut. 8, Supplement 7: 1-119.

21. Pereira, M. P. Barnwell and W. Bailes. 1987. Screening of Priority Chemicals for Reproductive Hazards. Monoethanolamine, Diethanolamine and Triethanolamine. Environmental health Research and Testing, Inc. Cincinnati, OH. Project # 200-84-2735.

22. SIDS Initial Assessment Report for Triethanolamine. UNEP Publications.

23. Smyth, H. F., Carpenter, C. P. and Weil, C. S. 1951. Range-finding toxicity data: List IV. Arc. Ind. Hyg. Occ. Med. 4: 119-22.

24. Zahn, R. and Wellens, H. 1980. Examination of Biological Degradability through the Batch Method – further Experience and New Possibilities of Usage. Z. Wasser Abwasser Frosch. 13: 1-7.

201-14950

General Information

CAS Number: 102-71-6
Common Name: Triethanolamine

II. Physical-Chemical Data

A. Melting Point

Test Substance
Identity: Triethanolamine
Remarks: None

Method
Method: Not stated.
GLP: No
Remarks: None

Results
Melting Point Value: 21°C
Remarks: None

Conclusions
The melting point was provided by a reliable resource. The endpoint has been adequately characterized.

Data Quality
Reliability: 2D
Remarks: Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference
Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

B. Boiling Point

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	Not stated
GLP:	No
Year:	Not stated
Remarks:	None

Results

Boiling Point Value:	335^{o}C
Remarks:	None

Conclusions The boiling point was provided in a reliable resource book. The endpoint has been adequately characterized.

Data Quality

Reliability:	2D
Remarks:	Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

C. Vapor Pressure

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Measured
GLP:	No
Remarks:	None

Results

Vapor PressureValue:	0.000477 Pa at 25^{o}C
Remarks:	None

Data Quality

Reliability:	2D
Remarks:	Reliable with restrictions; endpoint was provided in a reliable reference text.

Reference Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

D. Partition Coefficient – Entry 1 of 3

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Inkrementenmethode von Rekker mit Computerprogram der Firma CompuDrug Ltd.
GLP:	Not stated
Remarks:	None

Results

Log K_{ow}:	-2.53
Remarks:	None

Data Quality

Reliability:	2D
Remarks:	Reliable with restrictions.

Reference BASF AG. Labor fuer Umweltanalytik; unveroeffentlichte Untersuchung. 1989.

Other

Entry 2 of 3 for Partition Coefficient

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	OECD Guideline 107 – Partition Coefficient (n-octanol/water), Flask shaking method.
GLP:	Not stated
Year:	1991
Remarks:	None

Results

Log K_{ow}:	-2.3
Temperature:	25°C
Remarks:	None

Data Quality:

Reliability:	1A.
Remarks:	Reliable without restrictions; Guideline study.

Reference BASF AG. Analytisches Labor; unveroeffentlichte Untersuchung (J. Nr. 90P03095.03 vom 05.04.1991)

Other

Entry 3 of 3 for Partition Coefficient

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	Not stated
GLP:	Not stated
Year:	1990
Remarks:	None

Results

Log K_{ow}:	-1.59
Temperature:	$20^{o}C$
Remarks:	None

Data Quality:

Reliability:	2D
Remarks:	Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

E. Water Solubility

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Not stated
GLP:	Not stated
Remarks:	None

Results

Value:	Miscible
Temperature:	$25^{o}C$
Remarks:	None

Data Quality:

Reliability:	2D
Remarks:	Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference

Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

III. Environmental Fate Endpoints

A. Photodegradation – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Other (calculated)
GLP:	Not stated
Remarks:	None

Results

Hydroxyl radicals reaction:	
OH Rate Constant:	1.04 E-12 cm^3/molecule-sec
Degradation:	50% after 4 hours
Ozone reaction:	No ozone reaction estimation
Remarks:	None

Data Quality:

Reliability:	2D
Remarks:	Reliable with restrictions. Endpoint was provided in a reliable reference text.

Reference Atkinson, R. Inter. J. Chem. Knot 19: 799-828. 1987. Listed in: Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

Other

Entry 2 of 2 for Photodegradation

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Estimation
Model:	Atmospheric oxidation
Remarks:	None

Results

Hydroxyl radicals reaction:	
OH Rate Constant:	110 E-12 cm^3/molecule-sec
Half-Life:	1.16 hours
Ozone reaction:	No ozone reaction estimation
Remarks:	None

Data Quality:

Reliability:	2D
Remarks:	Reliable with restrictions. Endpoint was provided by computer modeling.

Reference: AopWin v.1.90. (EPI Suite™ v.3.10). Downloadable at http://www.epa.gov/oppt/exposure/docs/episuitedl.htm. ©2000 U. S. Environmental Protection Agency.

B. Stability in Water

Test Substance

Identity:	Triethanolamine
Remarks:	If released to water, Triethanolamine should biodegrade. The half-life of this compound is expected to range from a few days to a few weeks depending on the degree of acclimation of the system. Bioconcentration in aquatic organisms, adsorption to suspended solids and sediments, and volatilization are not expected to be important fate processes in water. Triethanolamine does not decompose or hydrolyze in contact with water and there is no abiotic degradation.

Reference Howard, P. H. Handbook of Environmental Fate and Exposure Data for Organic Compounds. Lewis Publishers. 1990.

C. Biodegradation – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	OECD Guideline 302B "Inherent biodegradability: Modified Zahn-Wellens Test"
Test type:	Aerobic
GLP:	Not stated
Year:	1979
Contact time:	8 days
Inoculum:	Activated sludge
Concentration:	400 mg/l
Remarks:	None

Results

Degradation:	82% after 8 days
Results:	Inherently biodegradable
Remarks:	None

Conclusions The biodegradability of the test substance has been adequately characterized.

Data Quality

Reliability:	1A
Remarks:	Reliable without restrictions; OECD guideline study.

Reference Gerike, P., Fischer, W. K. 1979. A Correlation Study of Biodegradability Determinations with Various Chemicals in Various Tests. ECETOX. Environ. Safety. 3: 159-173.

Other

Entry 2 of 2 for Biodegradation

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	OECD Guideline 302 B
Test type:	Aerobic
GLP:	Not stated
Year:	1980
Contact time:	14 days
Concentration:	1000 mg/l
Inoculum:	Domestic sewage
Remarks:	None

Results

Degradation:	89 % after 14 days
Results:	Inherently biodegradable
Kinetic:	Not stated
Breakdown products:	Not stated
Remarks:	None

Conclusions The biodegradability of the test substance has been adequately characterized.

Data Quality

Reliability:	1A
Remarks:	Reliable without restrictions; OECD guideline study.

Reference Zahn, R. and Wellens, H. 1980. Examination of Biological Degradability through the Batch method – further Experience and New Possibilities of Usage. Z. Wasser Abwasser Forsch. 13: 1-7.

Other

D. Transport between Environmental Compartments (Fugacity)

Test Substance

Identity:	Triethanolamine
Remarks:	None

Method

Method:	Calculation according to Mackay, Level I
Remarks:	Data used: Molecular mass: 149.2 Log10 octanol/water partition coefficient: -1.59 Water solubility: 10,000 mg/l (As triethanolamine is fully miscible with water, an estimated value as shown was used.) Vapor pressure: 0.000477 Pa at 25°C Amount of chemical dispersed: 10 moles

Results

Distribution to each medium

	Percent Distribution
Air	<0.001
Water	99.999
Soil	<0.001
Sediment	<0.001

Remarks: None

Reference Comber, M. I. H. Zeneca Brixham Environmental Laboratory. Letter to M. G. Penman. ICI Chemicals & Polymers Limited. 1993.

Other

IV. Ecotoxicity

A. Acute Toxicity to Fish – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	Static
Test type:	24-hour LC_{50}
Analytical monitoring:	No data
Organism:	*Carassius auratus* (goldfish, freshwater species)
Year:	1979
GLP:	No data
Statistical methods:	None
Remarks:	The test procedure was in accordance with American Public Health Association guideline. Goldfish of uniform length (average 6.2±0.7 cm) and weight (average 3.3 g) and in good health were used for the assay. Triethanolamine was tested at a series of concentrations. In each test 10 fish were exposed in 25 liters of solution (pH – 9.9; temperature – 20^{o}C) contained in all glass tanks. The solutions were aerated throughout the test period.

Results

LC_{50} (24 hours):	> 5000 mg/l
Remarks:	None

Conclusion The acute toxicity of the test substance has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Birdie, A. L., C. J. M. Wolff and M. Winter. 1979. The Acute Toxicity of Some Petrochemicals to Goldfish. Water Res. 13: 623-626.

Other

Entry 2 of 2 – Acute Toxicity to Fish

Test Substance

Identity:	Triethanolamine
Purity:	97 %
Remarks:	None

Method

Method:	Not stated
Test type:	Acute
GLP:	No data
Year:	1987
Species:	*Pimephales promelas*
Analytical monitoring:	Yes
Exposure period:	96 hours
Statistical methods:	None
Remarks:	The conditions of the test solutions were as follows: pH – 7.8; temperature – 25.7°C; dissolved oxygen – 7.3 mg/l.

Results

LC_{50} (96 hours):	11,800 mg/l
Remarks:	The affected fish lost schooling behavior, were hyperactive and darkly colored, had increased respiration and lost equilibrium prior to death.

Conclusion The acute toxicity of the test substance has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restriction; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Geiger, D. L., L. T. Brooks and D. J. Call. Acute Toxicities for Organic chemicals to Fathead Minnows (*Pimephales promelas*). Volume V. Center for lake Superior Environmental Studies, University of Wisconsin – Superior. 1984-88.

Other

B. Acute Toxicity to Daphnids – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	DIN 38412 part 11
Test type:	Acute static
GLP:	No data
Year:	1982
Species:	*Daphnia magna*
Analytical monitoring:	No
Exposure period:	24 hours
Statistical methods:	No statistics applied to data
Remarks:	Test medium was not neutralized. Concentrations were nominal.

Results

EC_{50} (24 hours):	1386 mg/l
EC_{100} (24 hours):	2455 mg/l

Conclusions The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Bringmann, G. and R. Kuhn. 1982. Z. Wasser Abwasser Forsch. 15: 6-11.

Other

Acute Toxicity to Daphnids – Entry 2 of 2

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	Not stated
Test type:	Acute static
GLP:	No data
Year:	1987
Species:	*Daphnia magna*
Analytical monitoring:	No
Exposure period:	24 hours
Statistical methods:	No statistics applied to data
Remarks:	Test was conducted at pH 7.6-7.7 and 20-22^{o}C.

Results

EC_{50} (24 hours):	1390 mg/l

Conclusions The 24-hour acute toxicity of the test substance to *Daphnia magna* has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Bringmann, G. and R. Kuehn. 1987. Results of the damaging effect of water pollutants on *Daphnia magna*. Z. Wasser Abwasser Forsch. 20: 161-166.

Other

C. Acute Toxicity to Aquatic Plants (Algae) – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	DIN 38412, Part 9
Test type:	Acute static growth inhibition
GLP:	Not stated
Year:	1986
Species:	*Scenedesmus subspicatus*
Analytical monitoring:	No
Exposure period:	96 hours
Statistical methods:	No statistics applied to data
Remarks:	The assay was conducted with and without neutralized triethanolamine. Concentrations were nominal.

Results

	Neutralized	Non-neutralized
EC_{10}:	13.2 mg/l	7.1 mg/l
EC_{50}:	910 mg/l	169 mg/l
EC_{90}:	62,500 mg/l	4030 mg/l

Conclusions The 96-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Amann, W. and A. Stainhauser. 1986. Umweltforschungsplan des BMI, UFOPLAN Nr. 102 05 308. im Auftrag des Umweltbundesamtes.

Other

Entry 2 of 2 – Acute Toxicity to Aquatic Plants (Algae) –

Test Substance

Identity:	Triethanolamine
Purity:	Not stated
Remarks:	None

Method

Method:	DIN 38412, Part 9
Test type:	Acute static growth inhibition
GLP:	Not stated
Year:	1990
Species:	*Scenedesmus subspicatus*
Analytical monitoring:	No
Exposure period:	72 hours
Statistical methods:	No statistics applied to data
Remarks:	None

Results

EC_{10}:	110 mg/l
EC_{50}:	750 mg/l

Conclusions The 72-hour acute toxicity of the test substance to *Scenedesmus subspicatus* has been adequately characterized.

Data Quality

Reliability:	2A
Remarks:	Reliable with restrictions; Acceptable, well-documented publication report which meets basic scientific principles.

Reference Kuhn, R. and M. Pattard. 1990. Results of the Harmful Effects of Water Pollutants to Green Algae (*Scenedesmus subspicatus)* in the Cell Multiplication Inhibition Test. Water. Res. 24: 31-38.

Other

V. Mammalian Toxicity

A. Acute Toxicity – Entry 1 of 5

Test Substance

Identity:	Triethanolamine
Purity:	91.8 % triethanolamine; 6.1 % diethanolamine
Remarks:	None

Method

Method/guideline followed:	Not stated
Type:	Oral toxicity
GLP:	No data
Year:	1973
Species/Strain:	Rat/strain not stated
Sex:	Male/Female
Number of animals/ sex/dose:	5
Vehicle:	Not stated
Route of administration:	Oral (gavage)
Remarks:	Five dose groups of 10 rats each were administered the test substance between 3.64 and 10.0 g/kg. Animals were observed for mortality and clinical signs for 14 days.

Results

Value:	LD_{50} is 7.39 g/kg
Mortality rate:	Not stated
Remarks:	There was slight to moderate degrees of hemorrhagic rhinitis in rats administered doses equal to or greater than 7.14 g/kg.

Conclusions

Remarks:	The acute oral LD_{50} is 7.39 g/kg.

Data Quality

Reliability:	2D
Remarks:	The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine,

Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235.

Acute Toxicity – Entry 2 of 5

Test Substance

Identity:	Triethanolamine
Purity:	Purity not stated
Remarks:	None

Method

Method/guideline followed:	Not stated
Type:	Oral toxicity
GLP:	No data
Year:	1951
Species/Strain:	Rat/strain not stated
Sex:	Males
Number of animals/ sex/dose:	6 animals/dose
Vehicle:	Water
Route of administration:	Oral (gavage)
Remarks:	None

Results

Value:	LD_{50} is 9.11 g/kg
Mortality rate:	Not stated
Remarks:	No clinical information given.

Conclusions

Remarks:	The acute oral LD_{50} is 9.11 g/kg.

Data Quality

Reliability:	2D
Remarks:	The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference

Smyth, H. F., Carpenter, C. P. and Weil, C. S. 1951. Range-finding toxicity data: List IV. Arc. Ind. Hyg. Occ. Med. 4: 119-22.

Acute Toxicity – Entry 3 of 5

Test Substance

Identity:	Triethanolamine
Purity:	Commercial grade
Remarks:	None

Method

Method/guideline followed:	Not stated
Type:	Oral toxicity
GLP:	No data
Year:	1940
Species/Strain:	Rat/strain not stated
Sex:	Not stated
Number of animals/ sex/dose:	10 animals/dose
Vehicle:	Test article was administered undiluted.
Route of administration:	Oral (gavage)
Dose range:	1 to 12 g/kg
Remarks:	None

Results

Value:	LD_{50} is 8 g/kg
Mortality rate:	Not stated
Remarks:	The average survival time after administration was 24 hours. The author states that mortality was probably the result of the alkalinity of the material. The gross pathological change was confined to the gastrointestinal tract. The stomach was distended, congested and showed hemorrhagic areas. The blood vessels of the large and small intestines were distended. Liver, kidney, spleen and lungs showed no gross pathological changes. Before death, most of the animals had an intense diarrhea and were completely prostrate.

Conclusions

Remarks:	The acute oral LD_{50} is 8 g/kg.

Data Quality

Reliability:	2D
Remarks:	The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference	Kindsvatter, V. H. 1940. Acute and chronic toxicity of triethanolamine. J. Indus. Hyg. Toxicol. 22 (6): 206-212.

Acute Toxicity – Entry 4 of 5

Test Substance

Identity:	Triethanolamine
Purity:	Purity not stated
Remarks:	None

Method

Method/guideline followed:	Per method used for inhalation toxicity at BASF
Type:	Inhalation toxicity
GLP:	No
Year:	1966
Species/Strain:	Rat/strain not stated
Sex:	Not stated
Number of animals/ sex/dose:	Not stated
Vehicle:	None
Route of administration:	Inhalation
Remarks:	The animals were exposed to a saturated atmosphere of triethanolamine for 8 hours at 20^{o} C.

Results

Value:	LC_{50} is greater than a saturated atmosphere.
Mortality rate:	No mortality.
Remarks:	No clinical information given.

Conclusions

Remarks:	The acute inhalation LC_{50} is greater than a saturated atmosphere.

Data Quality

Reliability:	2D
Remarks:	The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference BASF AG. 1966 Abteilung Toxikologie. Unpublished report. ZST-Nr. SV/307.

Acute Toxicity – Entry 5 of 5

Test Substance

Identity:	Triethanolamine
Purity:	91.8 % triethanolamine; 6% diethanolamine
Remarks:	None

Method

Method/guideline followed:	Not stated
Type:	Dermal toxicity
GLP:	No
Year:	1973
Species/Strain:	Rat/strain not stated
Sex:	Not stated
Number of animals/ sex/dose:	Not stated
Vehicle:	None
Route of administration:	Dermal
Remarks:	None

Results

Value:	LD_{50} is greater than 2 g/kg
Mortality rate:	None
Remarks:	No clinical information given.

Conclusions

Remarks:	The acute dermal LD_{50} is greater than 2 g/kg.

Data Quality

Reliability:	2D
Remarks:	The study is reliable with restrictions. Data appear solid, but report lacks details consistent with a guideline study.

Reference Cosmetic Ingredient Review. 1983. Final Report on the Safety Assessment of Triethanolamine, Diethanolamine and Monoethanolamine. J. Am. Coll. Toxicol. 2 (7): 173-235.

B. Genetic Toxicity – Entry 1 of 3

Test Substance

Identity:	Triethanolamine
Purity:	Reported as reagent grade
Remarks:	None

Method

Method:	Ames/*Salmonella* Bacterial Point Mutation Assay
Type:	Reverse mutation assay
Test system:	Bacteria
GLP:	Not stated
Year:	1982
Species/Strain:	*Salmonella typhimurium/* TA98 and TA100.
Metabolic activation:	Test conducted with and without metabolic activation.
Concentrations tested:	0 to 20,000 µg/plate
Remarks:	Triethanolamine was dissolved in 0.1 ml of distilled water and added to 0.5 ml of S9 mix or 0.1 M sodium phosphate buffer (pH 7.4) with 0.1 ml of bacterial culture. The mixtures were incubated for 20 minutes at 37^o C with shaking. It was then mixed rapidly with 2 ml of molten soft agar containing 0.1 µmole of L-histidine and biotin, poured onto minimal glucose agar plates and incubated for 2 days at 37^o C. S9 mix was prepared form the post-mitochondrial supernatant of the liver of rats that had been pretreated with polychlorinated biphenyl for induction of microsomal enzymes. Concurrent solvent (water) and positive controls (without activation – 4-nitroquinoline 1-oxide; with activation – benzo[a]pyrene) were tested with and without the metabolic activation systems.

Results There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation.

Conclusions

Remarks:	The test substance did not induce mutations in this test system with and without metabolic activation.

Data Quality

Reliability:	1B

Remarks: Reliable without restriction; comparable to guideline study.

Reference Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. Mut. Res. 101: 305-313.

Other

Genetic Toxicity – Entry 2 of 3

Test Substance

Identity:	Triethanolamine
Purity:	Reported as practical grade
Remarks:	None

Method

Method:	Ames/*Salmonella* Bacterial Point Mutation Assay
Type:	Reverse mutation assay
Test system:	Bacteria
GLP:	Not stated
Year:	1986
Species/Strain:	*Salmonella typhimurium/* TA98, TA100, TA 1535 and TA 1537.
Metabolic activation:	Test conducted with and without metabolic activation.
Concentrations tested:	0 to 3,333 µg/plate
Remarks:	Male Sprague-Dawley rats were used to prepare the S-9 fraction. Liver microsomal enzymes were induced with polychlorinated biphenyl (Arochlor 1254). The S-9 mix was prepared immediately prior to the assay and consisted of the following per ml: 0.04 M β-nicotinamide adenine dinucleotide phosphate, 0.10 ml; 0.05 M glucose-6-phosphate, 0.10 ml; 1.0 M NaH_2PO_4, pH 7.4), 0.10 ml; and distilled water, 0.56 ml. Triethanolamine was assayed in the preincubation assay. To each test tube maintained at 37^o C was added in the following order: 0.5 ml of S-9 mix or 0.1 M PO_4 buffer (pH 7.4), 0.05 ml of the overnight culture, and 0.05 ml of solvent or chemical dilution. The mixture was mixed and allowed to incubate without shaking at 37^o C for 20 minutes, at which time 2.0 ml of molten top agar supplemented with 0.5 mM L-histidine and 0.5 mM D-biotin were added. The contents of the tubes were mixed and pured onto 25 ml of minimal glucose bottom agar in 15 x 100-mm plastic petri dishes. When the top agar has solidified, the plates were nverted and incubated at 37^o C for 48 hours. Concurrent solvent (water) and positive controls (without activation – sodium azide for TA 1535 and TA 100, 4-nitro-o-phenylenediamine for TA 98, 9-aminoacridine for TA 1537; with activation – 2-aminoanthracene for

all strains) were tested with and without the metabolic activation systems.

Results

There was no difference between controls and all concentrations tested in revertant colonies/plate with or without metabolic activation.

Conclusions

Remarks: The test substance did not induce mutations in this test system with and without metabolic activation.

Data Quality

Reliability: 1B

Remarks: Reliable without restriction; comparable to guideline study.

Reference

Mortelmans, K., S. Haworth, T. Lawlor, W. Speck, B. Tainer and E. Zeiger. 1986. *Salmonella* Mutagenicity Tests: II. Results from the Testing of 270 Chemicals. Environ. Mut. 8, Supplement 7: 1-119.

Other

Genetic Toxicity – Entry 3 of 3

Test Substance

Identity:	Triethanolamine
Purity:	Reported as reagent grade
Remarks:	None

Method

Method:	That of Ishidate and Odashima (1977) as reported in Mutation Research 48: 337-354.
Type:	Cytogenetic assay
Test system:	Chinese hamster lung cells
GLP:	Not stated
Year:	1982
Species/Strain:	CHL cells
Concentrations tested:	0 to 100 μg/ml
Remarks:	Inocula of 2 x 10^4 CHL cells suspended in Eagle's MEM supplemented with 10% fetal calf serum were seeded into 60-mm petri dishes. After cultivation for 3 days, a test chemical was then added and incubation was continued for 24 or 48 hours. Colcemid was added to the media at a final concentration of 0.2 μg/ml for the last 2 hours of incubation. After trypsinization, the cells were incubated in hypotonic solution (0.075-M KCl) for 15 minutes at 37^o C. The cells were then fixed with ice-cold fixative (methanol:glacial acetic acid, 3:1) with 3 changes of the solution. A few drops of the cell suspension were placed on a slide on wet blotting paper, and the slide was stained with Giemsa. At each concentration of the chemical, 100 metaphase cells were examined for chromosomal aberrations. The controls consisted of a tissue culture control, vehicle control (DMSO) and a positive control (N-methyl-N'-nitro-N-nitrosoguanidine.

Results

There was no difference between controls and all concentrations tested in chromatid gaps, chromatid breaks, chromatid exchanges or number of polyploid cells.

Conclusions

Remarks: The test substance did not induce chromosome aberrations in this test system with and without metabolic activation.

Data Quality

Reliability: 1B

Remarks: Reliable without restriction; comparable to guideline study.

Reference Inoue, K., T. Sunakawa, K. Okamoto and Y. Tanaka. 1982. Mutagenicity tests and in vitro transformation assays on triethanolamine. Mut. Res. 101: 305-313.

Other

C. Repeated Dose Toxicity – Entry 1 of 2

Test Substance

Identity:	Triethanolamine
Purity:	88.5 % triethanolamine and 6 % diethanolamine
Remarks:	None

Method

Method/guideline followed:	Not stated
Test type:	Oral
Year:	1976
GLP:	No data
Species:	Rat
Strain:	Not stated
Number and sex:	20 males and 20 females/group. Animals were exposed to 4 dose levels ranging from 0 to 1000 mg/kg.
Route of administration:	Oral (incorporation into the feed)
Duration of test:	91 days
Control group and treatment:	No information on control group specified
Post-exposure observation period:	Not specified
Methods:	Animals were dosed for 91 days and then evaluated for hematologic effects and pathological change.

Results

NOAEL:	1000 mg/kg
Remarks:	No gross or histopathological evidence of a treatment-related effect. No significant hematologic effects.

Conclusions

Remarks:	Triethanolamine is of low toxicity from repeated exposure up to 91 days with a NOAEL of at least 1000 mg/kg.

Data Quality

Reliability (Klimisch):	2B
Remarks:	Reliable with restrictions. Basis data provided.

Reference: CTFA. 1976. Submission of data by CTFA (2-5-55). 91 Day subchronic oral toxicity using triethanolamine. Cited in CIR, 1983.

Other

Repeated Dose Toxicity – Entry 2 of 2

Test Substance

Identity:	Triethanolamine
Purity:	99 % reagent grade
Remarks:	None

Method

Method/guideline followed:	Not stated
Test type:	Oral
Year:	1986
GLP:	No data
Species:	Rat
Strain:	Fischer 344
Number and sex:	50 animals/sex/group
Route of administration:	Oral (incorporation into the drinking water)
Duration of test:	104 weeks
Dose level:	1 or 2 % triethanolamine in the drinking water. Mean daily water consumption values in control, low-dose, and high-dose groups of both sexes were 21.7, 20.7 and 21.8 ml/rat in males and 15.4, 18.2 and 17.7 ml/rat in females, respectively.
Control group and treatment:	Concurrent control group (50 rats/sex) administered the solvent (water).
Post-exposure observation period:	9 weeks
Methods:	Animals were randomly divided into 3 groups, each consisting of 50 rats/sex. Rats were given the test article solutions ad libitum. At week 60 loss of body weight gain and mortality rate increased in the females in the 2 % group. Therefore, the concentration of triethanolamine was reduced by one-half for the females in this group. Triethanolamine solutions were freshly prepared once/week and the amount of solution consumed was measured to calculate the triethanolamine intake. All animals were observed daily and clinical signs and mortality were recorded. Body weights were measured once/week during the first 13 weeks of the study and then once every 4 weeks. At the end of the treatment and observation periods the following organs were evaluated for

histopathological change: brain, spinal cord, peripheral nerves, pituitary, thyroid, thymus, lungs, heart, liver spleen, pancreas, adrenals, kidneys, urinary bladder, salivary glands, tongue, esophagus, stomach, duodenum, jejunum, ileum, cecum, colon, rectum, gonads, accessory genital organs, mammary glands, lymph nodes, skin, musculature, sternum, femur, eyes, and nasal cavity.

Results

Remarks: None of the treatment groups showed a significant increase in the incidence of any specific tumors over the corresponding control group values. Treatment-related nonneoplastic lesions were observed in the kidneys consisting of mineralization of the renal papilla, nodular hyperplasia of the pelvic mucosa and pyelonephritis with or without papillary necrosis. These findings were observed in a dose-response relationship in males and females from both the low and high dose groups. No other nonneoplastic treatment-related histopathological change was noted in any other organs.

Conclusions

Remarks: Triethanolamine is not carcinogenic and it does not produce histopathological change to the reproductive organs of either male or female rats when administered in the drinking water at dose levels up to approximately 900 mg/kg.

Data Quality

Reliability (Klimisch): 2A

Remarks: Reliable with restrictions. Acceptable, well-documented publication/study report that meets basic scientific principles.

Reference: Maekawa, A., H. Onodera, H. Tanigawa, K. Furuta, J. Kanno, C. Matsuoka, T. Ogiu, and Y. Hayashi. 1986. Lack of Carcinogenicity of Triethanolamine in F344 Rats. J. Toxicol. Environ. Health 19:345-357.

Other

D. Reproductive Toxicity

No studies have been conducted to specifically evaluate the effect of triethanolamine on reproductive performance. However, based on consideration of the repeat dose toxicity studies of at least 90 days duration, there were no abnormalities noted in the histopathological examination of reproductive organs. This fact, and the lack of effects on development, allow the conclusion that triethanolamine would not be expected to produce toxicity to reproductive performance and fertility. The OECD SIDS Initial Assessment Report (Report) concurs with this opinion. The Report states, "Although there were no studies available on fertility, there were no abnormalities noted in the histopathological examination of reproductive organs (testes and ovaries) in the 90-day oral and dermal toxicity studies. Triethanolamine is not toxic to development or the reproductive system."

E. Developmental Toxicity

Test Substance

Identity:	Triethanolamine
Purity:	Purest grade commercially available confirmed by gas chromatography (FID).
Remarks:	None

Method

Method/guideline followed:	Chernoff-Kavlock teratogenicity screening test
Test type:	Oral
GLP:	Yes
Species:	Mouse
Strain:	CD-1
Number and sex:	50 mated females in Phase III
Route of administration:	Oral gavage
Duration of test:	Through day 3 of post partum.
Dose level:	1125 mg/kg
Exposure period:	Exposure of females on days 6-15 of gestation.
Frequency of treatment:	The test article was administered daily on days 6-15 of gestation.
Control group and treatment:	Yes. Identical dosing regimen treatment group with vehicle.
Methods:	This study was conducted in 3 phases. Phases I and II were range finding studies designed as a method to identify the appropriate dose for phase III. Phase I was conducted using non-pregnant animals with administration of the triethanolamine daily for 5 consecutive days. Phase II (4 animals/dose) was conducted using pregnant animals with treatment on gestation 6-15. In phase III the animals were evaluated for the following: maternal body weight, maternal mortality and signs of toxicity, implantation sites, pup counts at birth with mortality and pup weight (recorded at birth and on day 3 postpartum).

Results	As a result of the mortality rate in the phase II pilot study, the dose chosen for phase III was 1125 mg/kg.
NOAEL (NOEL):	1125 mg/kg

Remarks: Oral administration of 1125 mg/kg triethanolamine to pregnant mice did not affect maternal mortality, the number of viable litters, length of gestation, litter size, percent survival of the pups or birth weight or weight gained by the pups.

Data Quality

Reliability (Klimisch): 1C

Remarks: Valid with restrictions; Study was conducted according to an established procedure used for screening chemicals for developmental toxicity.

Reference: Pereira, M., P. Barnwell and W. Bailes. 1987. Screening of Priority Chemicals for Reproductive Hazards. Monoethanolamine, Diethanolamine and Triethanolamine. Environmental Health Research and Testing, Inc. Cincinnati, OH. Project # 200-84-2735.

Other